

REMARKS

In the Office Action, claims 1, 2, 4-17, and 19-32 were rejected. Reconsideration and allowance of all pending claims are requested in view of the points set forth below.

Rejections Under 35 U.S.C. § 102

In the Office Action, claims 1, 2, 4-10, 13-17, 19, 22-31, and 32 were rejected under 35 U.S.C. §102(b) as being anticipated by Dumoulin '635. A *prima facie* case of anticipation under 35 U.S.C. §102 requires a showing that each limitation of a claim is found in a single reference, practice or device. *In re Donohue*, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). Applicants respectfully assert that the present invention, as recited in independent claims 1, 13, 23 and 32 is patentable over Dumoulin '635.

Independent claims 1, 13, 23 and 32 recite, in generally similar language, *repositioning the medical device within the target region of interest without moving the subject*. Independent claim 32 further recites *terminating therapy, activating an audio or text advisory feedback to the interface unit, or a combination thereof*.

Dumoulin '635 discloses stereoscopic tracking of the three-dimensional position and orientation of an invasive device within a subject without using X-rays. However, *Dumoulin '635 fails to disclose or suggest positioning of the medical device within the target region of interest without moving the subject*. Applicants respectfully submit that the positioning of the medical device within the target region of interest may be achieved in the present application by moving the medical device itself via a medical device positioning subsystem or a processor.

The Examiner, in his response to arguments, stated that Dumoulin '635 discloses a device for repositioning a medical device within the target region of interest without moving the subject. However, *Dumoulin '635 actually discloses automatic placement and alignment of the subject by use of a support arm within a desired region around*

invasive device. See, column 7, lines 24-27. Clearly, automatic placement and alignment of the subject by use of a support arm within a desired region around invasive device is not same as positioning a medical device within the target region of interest without moving the subject.

The Examiner, in his response to arguments, further stated that the imaging device disclosed in Dumoulin '635 is capable of both translational and rotational motion to facilitate any modifications in the area to be imaged. It is thus understood that the subject of the procedure would not be required to move during tracking and imaging. *Even if this were true, Applicants respectfully submit that tracking and imaging a medical device within a subject without moving the subject cannot be interpreted as positioning a medical device within the target region of interest without moving the subject.*

The Examiner, in his response to arguments, further stated that Figure 1 of Dumoulin '635 (erroneously referred to as the current specification) clearly shows the support arm for the imaging device moving and that the support arm is not connected to the support table at all. The Examiner then made a logical jump and stated that the support table (labeled 110) and the subject (labeled 112) are not moved, rather the support arm and the imaging apparatus seem to move to enable better viewing of the area of interest (column 7, lines 24-37). The Examiner further pointed to Dumoulin '635, column 27-30 and states that "[t]he calculated position of the invasive device from tracking computer is supplied to a positioning means which controls the position and orientation of the support arm in relation to support table" would imply that the moving parts (support arm) move in relation to the table and not the other way round. *Even if this were true, Applicants respectfully assert that positioning means which control the position and orientation of support arm in relation to support table cannot be interpreted as medical device positioning subsystem or processor that positions a medical device within the target region of interest.* Moreover, Dumoulin '635 clearly teaches **automatic placement and alignment of the subject by use of a support arm**

within a desired region around invasive device and not the other way round. *See, column 7, lines 24-27.*

The Examiner further added that in the claims of Dumoulin '635, specifically claims 3-5, Dumoulin discloses at least a device that is well known in the art to be capable of being moved relative to a patient without necessitating the movement of the patient (such as guide wire). The Examiner further stated that as is inherent with a device attached to a guide wire or simply a guide wire itself; the surgeon places and adjusts the position of the wire or device relative to the patient without moving the patient, based on the feedback from the imaging/locating device. *Again, even if this were true, Applicants respectfully submit that manually positioning an invasive device (by surgeon) while looking at the superimposed position of the invasive device in an X-ray image of the subject cannot be interpreted as automatically positioning the invasive device (through medical device positioning means or a processor) within the target region of interest.*

Additionally, the present application, discloses a positioning subsystem that is configured to respond to motion of at least one of the medical device or the subject in a predetermined or pre-programmed fashion when the position of the medical device deviates from the target region of interest. See, Application, page 10, lines 7-12; See also, page 9, lines 12-16. The Examiner argued that Dumoulin '635 teaches a monitoring subsystem that is responsive to the movement of the medical device relative to the target region within the subject by activating the imaging system to automatically move and acquire new/additional images without moving the subject. The examiner further argued that the monitoring subsystem disclosed in Dumoulin '635 provides advisory feedback to the interface unit when the medical device deviates from a target position via a visual icon representing the position of the device. Additionally, the Examiner argued that the feedback provided to the interface can be used to navigate the device to a region of interest.

Applicants, here again, respectfully submit that Dumoulin ‘635 does not disclose or suggest a medical device monitoring and positioning subsystem or a processor as recited in the claims. The monitoring subsystem disclosed in Dumoulin ‘635 is configured only to track the medical device within the subject by repeated acquisition of images. Dumoulin ‘635 further discloses a superimposed visual icon on the X-ray image of the subject to represent the tracked medical device. Applicants respectfully submit that *Dumoulin ‘635 do not disclose the claimed predetermined or pre-programmed response such as terminating therapy or repositioning the medical device within the target region of interest without moving the subject (as argued above) or activating an audio or a text advisory feedback to the interface unit.*

Further, the Examiner argued that Dumoulin ‘635 discloses positioning a medical device within the target region of interest without moving the subject as a predetermined response. However, as stated above, Dumoulin ‘635 discloses *automatic placement and alignment of the subject by use of a support arm within a desired region around invasive device based on the feedback and not navigating or repositioning the “medical device” during the medical procedure without moving the subject based on the feedback to the interface unit.*

Applicants, therefore, believe that in absence of the positioning subsystem that is configured to respond in a predetermined or pre-programmed fashion as described above, the present invention, as recited in the claims, is not enabled by Dumoulin ‘635.

At least because Dumoulin ‘635 fails to disclose or suggest a positioning subsystem that is configured to reposition the medical device within the target region of interest without moving the subject, as claimed, the reference cannot support a *prima facie* case of anticipation of claims 1, 13, 23 and 32. Claims 2, 4-10, 14-17, 19, 22 and 24-31 depend directly or indirectly from claims 1, 13, 23 and 32 respectively. Accordingly, the Applicants submit that claims 2, 4-10, 14-17, 19, 22 and 24-31 are

allowable by virtue of their dependency from allowable base claims. Applicants also submit that the dependent claims are further allowable by virtue of the subject matter they separately recite. Thus, it is respectfully requested that the rejection of claim 1, 2, 4-10, 13-17, 19, and 22-32 under 35 U.S.C. §102(b) be withdrawn.

Rejections Under 35 U.S.C. § 103

In the Office Action, claim 32 was rejected under 35 U.S.C. §103(a) as being unpatentable over Dumoulin '635. Claims 2, 11, 12, 20 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dumoulin '635 in view of Panescu. Claims 6, 17, and 24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dumoulin '635 in view of Twiss et al., U.S. Patent No. 5,375,596. Claims 1, 2, 4-10, 13-17, 19, and 22-31 were also rejected under 35 U.S.C. §103(a) as being unpatentable over Dumoulin '165 in view of Dumoulin '635. Claims 2, 11, 12, 20 and 21 were also rejected under 35 U.S.C. §103(a) as being unpatentable over Dumoulin '165 in view of Dumoulin '635 and further in view of Panescu.

For the same reasons set forth above, Dumoulin '635 alone or in combination with Dumoulin '165 does not teach, suggest or disclose each and every aspect of the invention claimed in independent claims 1, 13 and 23. Claims 2, 4-12, 14-17, 19-22, and 24-31 depend directly or indirectly from claims 1, 13 and 23 and are allowable by virtue of such dependency, as well as for the subject matter they separately recite. Thus, it is respectfully requested that the rejection of claims 1, 2, 4-17, 19-30 under 35 U.S.C. §103(a) be withdrawn.

Moreover, the Examiner failed to apply a reference that includes *all* of the recited features of claim 32. Applicants respectfully submit that Dumoulin '635 does not describe *any claimed predetermined or pre-programmed responses such as terminating therapy or repositioning the medical device within the target region of interest without moving the subject (as argued above) or activating an audio or a text advisory feedback*

to the interface unit whatsoever. Thus, Dumoulin '635 does not teach or suggest all of the recitations of the claim 32.

MPEP 2143.03 states that,

[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.

Applicants respectfully submit that, as stated above, there is no teaching or suggestion of *any claimed predetermined or pre-programmed responses* in Dumoulin '635. In view of the forgoing considerations, Applicants contend that the reference fails to establish a *prima facie* case of obviousness of claim 32. Claim 32 is therefore believed to be clearly patentable over the cited reference. Its consideration and allowance is respectfully requested.

Conclusion

In view of the remarks and amendments set forth above, Applicants respectfully request allowance of the pending claims. If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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